

INFORMED CONSENT

Reaching Adolescent Girls and Young Women (AGYW) Through Girl-Friendly Drug Vendors

ClinicalTrials.gov Identifier:

NCT04045912

Brief Title:

AmbassADDOrs for Health

Consent Form Date:

2 May 2019

Sponsor:

U.S. National Institutes of Health



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WAZEE NA WATOTO



HEALTH FOR A PROSPEROUS NATION

CONSENT TO PARTICIPATE IN RESEARCH

AmbassADDOrs for Health

Introduction

My name is _____ and I am working for Dr. Prosper Njau of Health for a Prosperous Nation and Dr. Angela Ramadhani, a Program Manager for the AIDS Control Program at the Tanzania Ministry of Health, Community Development, Gender, Elderly, and Children. I am also working with Professors Jenny Liu and Sandra McCoy at the University of California to conduct a research study, which I invite you to participate in. We are asking you to take part in the study because you own an accredited drug-dispensing outlet (ADDO) or pharmacy in Shinyanga.

Purpose

The purpose of this research study is to understand whether local drug shops might be an effective way to reach adolescent girls and young women with reproductive health services.

Procedures

If you agree to participate in this research study, you will be asked to do the following:

- **Survey:** You will be asked to complete a survey about your drug shop's daily operations and products and services that are available at the shop. The survey also includes some questions about your background and your experiences providing these products and services to people in your community.
- **Randomization:** You will be randomly assigned to one of the two study groups described below. This means that the group you are in will be chosen by chance, like the flip of a coin. You cannot choose the group you will be in.

Both groups will be provided with a four-month supply of HIV self-test kits to distribute at their drug shops (~30 kits per month). Half of these kits will be reserved for adolescent girls and young women who visit your shop and must be provided to them for free. The other half of these kits can be sold to other customers at your shop at a suggested price.

- If you are in Group 1, you will be asked to implement several new marketing strategies in your shop which are designed to appeal to adolescent girls and young women. As a part of these marketing strategies, you will be provided with a variety of products to give to adolescent girls and young women, in addition to the HIV self-test kits.
- If you are in Group 2, you will receive the HIV self-test kits, but you will not receive any additional products or marketing strategies.
- **Shop observations:** A research assistant will quietly observe your shop during business hours to record information about how many people visit the shop and the products and services that they receive. There will be up to 12 observations over the



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next five months, and each observation will last up to 4 hours. The researcher will not interfere with any of your regular business activities and will not interact with any of your customers.

- Shop records: You and your employees will be asked to maintain daily records of when certain products and services are provided in your shop using a form that we will give you.
- Customer exit surveys: On certain days, a research assistant will be posted outside of your shop in order to survey some of your customers about their shopping experience. The researcher will not interfere with any of your regular business activities or interact with customers while they are in your shop.

Study time

Participation in this study will involve a one-time survey, which can be conducted today or at a future day and time of your choosing; the survey will take about 15 to 30 minutes.

Maintaining shop records over the four-month study period may take you or your employees at most 10 minutes per business day. Other activities will not require any additional time from you.

Study location

We can arrange for the survey to be conducted at the time and place of your choosing, including here and now. We can also conduct the survey at our private office located at the Shinyanga Regional Hospital. The rest of the study activities will take place at your drug shop.

Benefits

If you agree to participate in this study, we will provide you with a four-month supply of HIV self-test kits for free (~30 kits per month, each valued at \$4 USD), and you will be able to sell half of these kits to shop customers and keep the profits.

Risks/Discomforts

There are some risks and/or discomforts associated with the study:

- Some of the research questions may make you uncomfortable. You are free to decline to answer any questions you don't wish to, or end the survey at any time.
- Some of the forms in this study contain personal identifying information, and there is a small chance that this could result in a breach of confidentiality. However, we are doing everything we can to make sure that this does not happen.

Confidentiality

Your study data will be handled as confidentially as possible. To minimize the risks of loss of confidentiality, we will do the following:

- Any study information in the study database will not include your name and contact



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information. All of your information will instead be identified with a random code.

- Your research records will always be securely stored. Paper forms will be stored in a locked cabinet in a locked office in a secured building. Computer files or databases that contain your data will be stored in an encrypted format on password-protected computers and will require a password so that only authorized study personnel have access.
- Publications or presentations with results of this study will not use individual names or other personally identifiable information.

Future use of study data

The research data will be maintained for possible use in future research by the research team or others. We will retain this data for up to 10 years after the study is over. The same measures described above will be taken to protect confidentiality of this study data.

Compensation/Payment

You will not be compensated for your participation in this study beyond the products that will be supplied to you each month.

Costs

You will not be charged for any of the study activities.

Treatment and Compensation for Injury

It is important that you promptly tell Dr. Prosper Njau or another member of the research staff if you believe that you have been injured because of taking part in this study. You can tell him in person or call him at [redacted].

Rights

Participation in research is completely voluntary.

You have the right to decline to participate or to withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. You may refuse to answer any question or leave at any time for any reason including feeling distressed or uncomfortable.

Questions

If you have any questions or concerns about this study, you can ask me or you can contact our office or Dr. Prosper Njau at [redacted] at any time. If you would like to direct your question to the international study team directly, you can contact Dr. Sandra McCoy in the United States at [redacted] or Dr. Jenny Liu in the United States at [redacted].

If you have any questions or concerns about your rights and treatment as a research subject, you may contact the National Institute for Medical Research at +255 22 2121400 or the office of the University of California, San Francisco's Institutional Review Board at +1 415 476 1814.



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Consent

You have been given a copy of this consent form to keep. If you wish to participate in this study, please sign and date below.

Participant's Name (*please print*)

Date

Participant's Signature

Date

Participant's Thumbprint (if unable to sign)

Date

Person Obtaining Consent

Date